MAY - 5 2004

510(k) Summary

Submission Information

Name and Address of Sponsor:	Howmedica Osteonics Corp. DBA (doing business as) Stryker Orthopaedics 325 Corporate Drive Mahwah, New Jersey 07430
For Information contact:	Margaret F. Crowe Regulatory Affairs Consultant Howmedica Osteonics Corp. (DBA Stryker Orthopaedics) 325 Corporate Drive Mahwah, New Jersey 07430

Device Identification

Proprietary Name:	Triathlon™ Cruciate Retaining (CR) Total Knee System
Common Name:	Cruciate Retaining Total Knee Replacement
Classification Name and Reference:	Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis 21 CFR §888.3560
Proposed Regulatory Class:	Class II
Device Product Code:	OR (87) JWH Prosthesis, Knee Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/ Polymer

The Triathlon™ CR Total Knee System consists of a femoral component, tibial insert, and all-polyethylene patellar components that are intended to be used with the previously cleared Triathlon™ Primary Cemented Tibial Tray in primary or revision total knee arthroplasty. The Triathlon™ All Polyethylene Patellar components are intended to be used with the femoral components of the previously released Duracon® Total Knee System, as well as the previously released Triathlon™ PS Femoral component in

situations where replacement of the articular surface of the patella is required. The Triathlon™ CR Total Knee System is intended to accommodate the posterior cruciate ligament (PCL) if it is present. Specific indications and contraindications are listed below:

Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or, rheumatoid arthritis
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques.

Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Distant foci of infection which may cause hematogenous spread to the implant site
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Obesity. An overweight or obese patient can produce loads on the prosthesis that can lead to failure of the fixation of the device or to failure of the device itself.

Device Description

The Triathlon™ Cruciate Retaining (CR) Total Knee System consists of three primary components: Triathlon™ Cruciate Retaining (CR) Femoral Component, Triathlon™ Cruciate Retaining (CR) Tibial Insert, and Triathlon™ Patellar components (available in two styles – symmetric and asymmetric). These components are intended to be used with the previously cleared Triathlon™ Primary Cemented Tibial Tray in primary or revision total knee arthroplasty. The Triathlon™ Patellar components are intended to be used with both the Triathlon™ CR Femoral component, the previously cleared Triathlon™ PS Femoral component, or the femoral components of the Duracon® Total Knee System. Duracon® patellar components may be used with both the Triathlon™ PS and Triathlon™ CR femoral components. The use of a patellar component is optional. The Triathlon™ CR components are described below:

The Triathlon™ Total Knee Cruciate Retaining (CR) Femoral Component is fabricated from cast cobalt-chromium-molybdenum alloy, and is intended for cemented application to replace the articulating surface of the distal femur. This cruciate retaining femoral component is utilized when total knee replacement is indicated, and accommodates the posterior cruciate ligament if it is present.

The Triathlon™ Total Knee Cruciate Retaining (CR) Femoral Component is available in right and left configurations, and eight proportional sizes (sizes 1 to 8) to accommodate differences in patient anatomy. The interior surface of the component is grit-blasted to increase surface roughness - this is intended to promote interdigitation of the polymethylmethacrylate (PMMA) bone cement with the surface texture and the apposing bone. This femoral component features cast-in pegs to help in femoral component placement, and to provide rotational stability.

The Triathlon™ Cruciate Retaining (CR) Tibial Insert is neutral in configuration, and is available in seven proportional sizes (sizes 2 to 8) and varying thicknesses (9mm, 11mm, 13mm, 16mm, and 19mm). The insert is fabricated from ultra high molecular weight polyethylene and cobalt-chromium alloy. The minimum thickness of the tibial insert on the bearing surface is 6mm. The tibial insert is designed to accommodate the posterior

cruciate ligament if it is present. There is a relief on the anterior aspect of the tibial insert to accommodate the patellar tendon and patellar fat pad.

The Triathlon™ CR Tibial Insert incorporates a locking wire feature on the anterior aspect of the insert. This locking wire is fabricated from cobalt-chromium alloy, and engages under tabs on the anterior rim of the Triathlon™ Primary Tibial Baseplate. This wire-tab locking mechanism secures the insert into the baseplate. This insert-baseplate locking mechanism is identical to the locking mechanism utilized on the Triathlon™ PS Total Knee System.

Triathlon™ Patellar components are available in two styles: symmetric and asymmetric. Both are fabricated from ultra high molecular weight polyethylene. The symmetric design is available in six diameters (27mm, 29mm, 31mm, 33mm, 36mm, and 39mm) and four thicknesses (8mm, 9mm, 10mm, and 11mm). The symmetric design features a central cement recess, and three pegs on the bone interface surface. The Triathlon™ Symmetric patellar component is intended to be implanted via a resurfacing or inset surgical technique. The asymmetric design is available in five superior/inferior dimensions (29mm, 32mm, 35mm, 38mm, and 40mm) and three thicknesses (9mm, 10mm, and 11mm). The asymmetric design features a flare on the lateral aspect of the component. The asymmetric patellar component also has a central recess with three pegs for cement fixation. The Triathlon™ Asymmetric patellar component is intended to be implanted using a resurfacing surgical technique.

Equivalent products include:

1. Triathlon™ PS Total Knee System
2. Duracon® CR Femoral Component
3. Scorpio® CR Femoral Component
4. Duracon® A/P Lipped Tibial Insert
5. Duracon® Symmetric Patellar Component
6. Duracon® Asymmetric Patellar Component
7. Kinemax® All Polyethylene Patella

Testing was presented to support a claim of substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2004

Ms. Margaret F. Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K040267
Trade/Device Name: Triathlon™ Cruciate Retaining (CR) Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint, patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: February 4, 2004
Received: February 5, 2004

Dear Ms. Crowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040267 (pg 1 of 2)

Indications for Use

510(k) Number (if known): K040267

Device Name: Triathlon™ CR Total Knee System

Indications For Use:

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040267

The Triathlon™ CR Total Knee System consists of a femoral component, tibial insert, and all-polyethylene patellar components that are intended to be used with the previously cleared Triathlon™ Primary Cemented Tibial Tray in primary or revision total knee arthroplasty. The Triathlon™ All Polyethylene Patellar components are intended to be used with the femoral components of the previously released Duracon® Total Knee System, as well as the previously released Triathlon™ PS Femoral component in situations where replacement of the articular surface of the patella is required. The Triathlon™ CR Total Knee System is intended to accommodate the posterior cruciate ligament (PCL) if it is present. Specific indications and contraindications are listed below:

Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or, rheumatoid arthritis
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques.

Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Distant foci of infection which may cause hematogenous spread to the implant site
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Obesity. An overweight or obese patient can produce loads on the prosthesis that can lead to failure of the fixation of the device or to failure of the device itself.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

K040267 (pg 2 of 2)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040267